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ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/553,317	RUDOLPH ET AL.	
	Examiner	Art Unit	
	RONALD T. NIEBAUER	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-14 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-14,16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendments and arguments filed 3/28/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Claims 2,15,19 have been cancelled. Claims 1,3-14,16-18 remain under consideration.

Oath/Declaration

The new oath/declaration submitted 3/28/08 is proper and the inconsistency in the filing date of the priority application has been corrected.

Claim Rejections - 35 USC § 112

This 112 second paragraph rejection is necessitated by applicants amendments to the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,3-6,10-14,16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites 'the method of claim 15'. There is insufficient antecedent basis for this limitation in the claims since claim 15 has been canceled. As such, the metes and bounds of claim 16 is unclear.

Claim 1 and dependent claims 3-6,10-14,17-18 refer to 'synthetic TA1 having substantially the same sequence as naturally occurring TA1 and recombinant TA1 having substantially the same sequence as naturally occurring TA1'.

The term 'substantially' in claim 1 is a relative term which renders the claim indefinite. The term 'substantially' is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the instant case, the specification does not provide a specific definition of 'substantially'. In paragraph 13, it is recited that modified sequences possess bioactivity substantially similar to that of TA1, e.g., a TA1 derived peptide having sufficient amino acid homology with TA1 such that it functions in substantially the same way with substantially the same activity as TA1. However, such paragraph does not clearly set forth the metes and bounds of the claim.

This 112 1st paragraph rejection (written description) is necessitated by applicants amendments to the claims. It is noted that there was a similar rejection in the previous office action, due to the claim amendments the rejection has been rewritten with respect to the instant claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,3-6,10-14,16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of

obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to methods of treatment comprising administering an alpha thymosin peptide selected from a group including (claim 1) 'synthetic TA1 having substantially the same sequence as naturally occurring TA1 and recombinant TA1 having substantially the same sequence as naturally occurring TA1'.
Although unclear (see 112 2nd) for purposes of examination 'substantially the same sequence' has been given its broadest reasonable interpretation such that at least some sequence similarity is maintained. Although unclear (see 112 2nd) for purposes of examination claim 16 has been

given its broadest reasonable interpretation such that it is also drawn to peptides including those with substantially the same sequence.

(1) Level of skill and knowledge in the art:

The level of skill in the art is high.

(2) Partial structure:

The claims recite the administration of an alpha thymosin peptide selected from a group including (claim 1) 'synthetic TA1 having substantially the same sequence as naturally occurring TA1 and recombinant TA1 having substantially the same sequence as naturally occurring TA1'. As discussed above, although unclear (see 112 2nd) for purposes of examination 'substantially the same sequence' has been given its broadest reasonable interpretation such that at least some sequence similarity is maintained. There are many peptides within the genus. For example when considering sequences that are substantially the same, if only 5 amino acids of TA1 were substituted with any of the 20 naturally occurring amino acids there would be over 3 million different peptide sequences possible. Hence, there is substantial variability in the genus.

No specific examples other than naturally occurring TA1 are provided in the specification. No specific examples are provided of sequences substantially similar thereto. Since there are a substantial variety of polypeptides possible within the genus, the examples do not constitute a representative number of species and do not sufficiently describe the genus claimed (see Gostelli above).

(3) Physical and/or chemical properties and (4) Functional characteristics:

The claims recite that the alpha thymosin peptide is to be useful for treating or preventing coronavirus infection. There is no correlation provided between function and structure. No direction is provided as to what core sequence is necessary to treat and prevent coronavirus

infection. In particular, there are no common structural attributes that identify the members of the genus. There is no teaching in the specification regarding which/how many residues of the structure can be varied while retaining the ability to prevent or treat coronavirus infection. There is no disclosure relating similarity of structure to conservation of function. One of skill in the art would not recognize which peptides would be useful for treating or preventing coronavirus infection. Thus, one skilled in the art would not conclude that applicant was in possession of the claimed genus.

(5) Method of making the claimed invention:

No examples are provided. The specification refers to other documents involving the use of the TA1 peptide (section 0026).

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 1 and dependent claims 3-6,10-14,16-18 is/are broad and generic, with respect to all possible peptides encompassed by the claims. The possible structural variations are many. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the polypeptides beyond those polypeptides specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of polypeptides identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of polypeptides embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Response to Arguments 112 written description

Since the claims have been amended, a new rejection adapted to the claims is recited above. Applicants arguments will be considered to the extent that they apply to the current rejection and claim set.

Applicants argue that the claims have been amended and that the skilled reader would readily accept that the inventors possessed the thymosin alpha 1 peptides and the methods claimed using them.

Applicant's arguments filed 3/28/08 have been fully considered but they are not persuasive.

As amended the claims read on an alpha thymosin peptide selected from a group including (claim 1) 'synthetic TA1 having substantially the same sequence as naturally occurring TA1 and recombinant TA1 having substantially the same sequence as naturally occurring TA1'. As discussed above, although unclear (see 112 2nd) for purposes of examination 'substantially the same sequence' has been given its broadest reasonable interpretation such that at least some

sequence similarity is maintained. There are many peptides within the genus. No specific examples other than naturally occurring TA1 are provided in the specification. No specific examples are provided of sequences substantially similar thereto. Since there are a substantial variety of polypeptides possible within the genus, the examples do not constitute a representative number of species and do not sufficiently describe the genus claimed. Further, there is no correlation provided between function and structure. There is no teaching in the specification regarding which/how many residues of the structure can be varied while retaining the ability to prevent or treat coronavirus infection. There is no disclosure relating similarity of structure to conservation of function.

This 112 1st paragraph rejection (enablement) is necessitated by applicants amendments to the claims. It is noted that there was a similar rejection in the previous office action, due to the claim amendments the rejection has been rewritten with respect to the instant claims.

Claims 1,3-14,16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

> The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are:

(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention:

The claims are drawn to methods of prevention or treating of respiratory coronavirus infection, specifically SARS (claim 3).

Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "therapeutic" or "treat", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes).

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

The state of the art in treating and preventing coronavirus infection is unpredictable. The Merck Manual (on-line version www.merck.com/mmhe severe acute respiratory syndrome entry) teach (last paragraph) that doctors may treat SARS with drugs. 'However, there is no evidence that these or any other drugs are effective'. Further (last sentence), it is stated that effective treatments and preventative vaccines are still in the research stage. Fujii et al. (J Infect Chemother 2004 10:1-7) summarize clinical reports of attempted treatment of SARS. Fujii et al. state (page 1 column 2 line 17) that 'the treatment of SARS remains largely anecdotal, and no treatment consensus has yet been reached'. In the same paragraph Fujii et al. state that 'until we have efficacious vaccines and specific anti-SARS-CoV agents, SARS is likely to remain a major

health threat to the world'. Holmes (Journal of Clinical Investigation 2003 11:1605-1609) state that (page 1607 2nd column first full paragraph) there are no approved antiviral drugs that are highly effective against coronaviruses. On page 1608 (last paragraph) Holmes states that 'development of effective drugs and vaccines for SARS is likely to take a long time'. Taken together, treatment of SARS is unpredictable and prevention has yet to be reported.

(5) The relative skill of those in the art:

The level of skill in the art is high.

(2) The breadth of the claims

The claims are drawn to methods of prevention or treating of respiratory coronavirus infection, specifically SARS (claim 3).

In addition to SARS, Holmes teach (page 1605 2nd column first complete paragraph) that coronaviruses are known as the cause of certain colds. Holmes teach (page 1605 last paragraph) that coronaviruses cause diseases in livestock, poultry and rodents. In addition to SARS, Holmes recites numerous other coronaviruses (page 1606 first column) including FIPV,HEV,IBV,MHV,and TGEV for example.

The composition used in the treatment includes an alpha thymosin peptide selected from a group including (claim 1) 'synthetic TA1 having substantially the same sequence as naturally occurring TA1 and recombinant TA1 having substantially the same sequence as naturally occurring TA1'. As discussed above, although unclear (see 112 2nd) for purposes of examination 'substantially the same sequence' has been given its broadest reasonable interpretation such that at least some sequence similarity is maintained. There are many peptides within the genus.

Further, the TA1 can be conjugated to polymers such as those recited in section 0022-0023 of the specification.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification is void of any working examples. The specification (section 0016) states that contemplated treatments include immune-stimulating-effective amounts of the TA1 peptide. Applicants refer to prior art involving conjugating peptides to polymers (section 0025) and use of the TA1 peptide (section 0026). However, a correlation or evidence that immune-stimulation is adequate for prevention or treatment of SARS has not been provided. One of skill in the art would not equate the asserted immune stimulating activity of TA1 with the ability to prevent or treat any and all coronavirus infections. Further, the specification does not provide any correlation between TA1 or substantially similar sequences, or PEGTA1 or PEGTA1 in combination with an interferon, and their ability to prevent and treat any and all coronavirus infections. Such guidance is necessary because the prior art cited above teach that the treatment and prevention of coronavirus infections is unpredictable. Accordingly one would be burdened with undue experimentation to determine if the peptides of the current invention could be used in methods of prevention or treatment.

(8) The quantity of experimentation necessary:

Experimentation is required in numerous areas particularly related to how to use the method and determination if it would be useful for the treatment and prevention of any and all coronavirus infections. Considering the state of the art as discussed by the references above, particularly with regards to the high unpredictability in the art as evidenced therein, and the lack

of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

Response to Arguments 112 enablement

Since the claims have been amended, a new rejection adapted to the claims is recited above. Applicants arguments will be considered to the extent that they apply to the current rejection and claim set.

Applicants argue that the previous Office Action does not state why the reader would require any experimentation. Applicants argue that the specification points to administration for prevention to persons at high risk and that the claims do not recite 'totally prevented'. Applicants argue that SARS is of fairly recent origin. Applicants argue that the claims as amended are no longer broad. Applicants argue that the specification provides detailed guidance and gives a great deal of guidance. Applicants argue that experimentation is not undue.

Applicant's arguments filed 3/28/08 have been fully considered but they are not persuasive.

As mentioned in the previous and current office action 'Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404)'. As such, the rejection as a whole sets forth why there would be experimentation necessary, specifically undue experimentation.

Although applicants argue that the specification points to administration for prevention to specific persons, limitations from the specification are not read into the claims. Although

applicants argue that the claims do not recite 'totally prevented', it is noted that the claims do recite 'prevention' and not 'partial prevention'. As such, the claims are drawn to prevention.

Although applicants argue that SARS is of fairly recent origin, such an argument does not provide factual information to show that one skilled in the art would have been able to make and use the claimed invention. In particular, of the numerous references cited related to the unpredictability in the art, applicant has provided no arguments related to the information cited in the references. Further, applicant has not provided any additional references or facts related to the predictability of the art.

Although applicants argue that the claims are not broad with respect to compounds for treatment, the composition used in the treatment includes an alpha thymosin peptide selected from a group including (claim 1) 'synthetic TA1 having substantially the same sequence as naturally occurring TA1 and recombinant TA1 having substantially the same sequence as naturally occurring TA1'. As discussed above, although unclear (see 112 2nd) for purposes of examination 'substantially the same sequence' has been given its broadest reasonable interpretation such that at least some sequence similarity is maintained. There are many peptides within the genus.

Although applicants assert that detailed guidance is provided, it is noted that the specification is 6 pages in total. The specification does not address the unpredictability of the art as evidenced by numerous references cited in the previous rejection

Further, section 716.09 of the MPEP states

> Once the examiner has established a prima facie case of lack of enablement, the burden falls on the applicant to present persuasive arguments, supported by suitable proofs where necessary, that one skilled in the art would have been able to make and use the claimed

invention using the disclosure as a guide. In re Brandstadter, 484 F.2d 1395, 179 USPQ 286 (CCPA 1973).

In the instant case, persuasive arguments and suitable proofs and facts have not been provided by the applicant.

With respect to arguments that there is no undue experimentation, as mentioned above and in the previous and current office action 'Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404)'. As such, the rejection as a whole sets forth why there would be experimentation necessary, specifically undue experimentation.

Further, the previous and current rejection state that it is undue 'to determine if the peptides of the current invention could be used in methods of prevention or treatment' 'Experimentation is required in numerous areas particularly related to how to use the method and determination if it would be useful for the treatment and prevention of any and all coronavirus infections. Considering the state of the art as discussed by the references above, particularly with regards to the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.'

Claim Rejections - 35 USC § 102

This 102b rejection is necessitated by applicants amendments to the claims. It is noted that there was a similar rejection using the same reference was made in the previous office action. Due to the claim amendments the rejection has been rewritten with respect to the instant claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-12,16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Sherman et al. (Hepatalogy, v27 1998, p.1128-1135).

Sherman teach the administration of thymosin alpha 1 and interferon to patients (title, abstract lines 13-16, Table 2). Sherman specifically teach a dosage of 1.6 mg of thymosin alpha 1 (abstract line 15) (compare claims 1-9 of the current invention). Sherman teach that the interferon that is administered in combination is an alpha interferon specifically alpha 2b (page 1128 column 2 line 12 of the first full paragraph) (compare claims 10-11 of the current invention). Sherman teach a dosage of 3MU of the interferon (abstract line 15-16) (compare claim 12 of the current invention). Sherman teach that the alpha thymosin administration is subcutaneous (abstract line 15) (compare claim 17 of the current invention).

It is noted that the current claim is drawn to a method of prevention. Since a method of prevention is used on a patient population prior to the onset of the ailment/disorder, any patient population is available for preventative administrations. A method of prevention is not carried out for a patient population that already has the ailment/disorder. As such, the human patients of Sherman (Table 1 for example) meet the claim limitations.

It is noted that claim 17 recites that the peptide is 'substantially continuously maintained'. A broad, reasonable interpretation of the claim includes the subcutaneous administration described by Sherman (abstract line 15).

Although unclear (sec 112 2nd) for purposes of examination 'substantially the same sequence' has been given its broadest reasonable interpretation such that at least some sequence similarity is maintained. Although unclear (sec 112 2nd) for purposes of examination claim 16 has been given its broadest reasonable interpretation such that it is also drawn to peptides including those with substantially the same sequence.

Response to Arguments 102

Since the claims have been amended, a new rejection adapted to the claims is recited above. Applicants arguments will be considered to the extent that they apply to the current rejection and claim set.

Applicants argue that Sherman does not teach any method expressly for treatment of SARS. Applicants argue that the specification teach specific persons to treat. Applicants argue that SARS did not exist at the time of the Sherman reference.

Applicant's arguments filed 3/28/08 have been fully considered but they are not persuasive.

It is noted that the claims are drawn to methods of prevention 'in a patient'. The claims do not recite that the patient has SARS. As such, since a method of prevention is used on a patient population prior to the onset of the ailment/disorder, any patient population is available for preventative administrations. Sherman teach the active steps of the instant claims.

Although applicants argue that the specification points to administration for prevention to specific persons, limitations from the specification are not read into the claims.

Although applicants argue that SARS did not exist at the time of the Sherman reference, it is noted that Sherman teach the active steps of the instant invention. Further, a method of prevention is used on a patient population prior to the onset of the ailment/disorder.

Double Patenting

This double patenting rejection is necessitated by applicants amendments to the claims. It is noted that there was a similar rejection in the previous office action. Due to the claim amendments the rejection has been rewritten with respect to the instant claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,3-9,13,16-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/535,835 ('835). Although the conflicting claims are not identical, they are not patentably distinct from each other.

'835 teach the administration of an alpha thymosin peptide, specifically thymosin alpha1 (claim 2) wherein the peptide administered at 1.6 mg (claim 5). '835 teach the alpha thymosin peptide conjugated to a polymer (claim 18), and teach administration by infusion (claim 16).

It is noted that the current claim is drawn to a method of prevention. Since a method of prevention is used on a patient population prior to the onset of the ailment/disorder, any patient population is available for preventative administrations. A method of prevention is not carried out for a patient population that already has the ailment/disorder. As such, the subjects of '835 meet the claim limitations.

Although unclear (see 112 2nd) for purposes of examination 'substantially the same sequence' has been given its broadest reasonable interpretation such that at least some sequence similarity is maintained. Although unclear (see 112 2nd) for purposes of examination claim 16 has been given its broadest reasonable interpretation such that it is also drawn to peptides including those with substantially the same sequence.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The claims recited above are directed to an invention not patentably distinct from the recited claims of commonly assigned 10/535,835.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/535,835, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Response to Arguments Double Patenting 10/535,835

Since the claims have been amended, a new rejection adapted to the claims is recited above. Applicants arguments will be considered to the extent that they apply to the current rejection and claim set.

Applicants argue that the claims do not relate to coronavirus treatment.

Applicant's arguments filed 3/28/08 have been fully considered but they are not persuasive.

It is noted that the current claim is drawn to a method of prevention. Since a method of prevention is used on a patient population prior to the onset of the ailment/disorder, any patient

population is available for preventative administrations. A method of prevention is not carried out for a patient population that already has the ailment/disorder.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ronald T Niebauer/
Examiner, Art Unit 1654

/Anish Gupta/
Primary Examiner, Art Unit 1654